

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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ABBOTT LABORATORIES and  
FOURNIER LABORATORIES  
IRELAND LTD.,

Plaintiffs,

v.

LUPIN LTD. et al.,

Defendants.

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**Hon. Dennis M. Cavanaugh**

**OPINION**

Civil Action No. 10-1578 (DMC-JAD)

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ABBOTT LABORATORIES and  
FOURNIER LABORATORIES  
IRELAND LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, et al.,

Defendants.

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Civil Action No. 10-2073 (DMC-JAD)

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ABBOTT LABORATORIES and  
FOURNIER LABORATORIES  
IRELAND LTD.,

Plaintiffs,

Civil Action No. 10-2139 (DMC-JAD)

v. :  
:  
WATSON LABORATORIES, INC.- :  
FLORIDA, et al., :  
:  
Defendants. :

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ABBOTT LABORATORIES and :  
FOURNIER LABORATORIES :  
IRELAND LTD., :

Plaintiffs, :

v. :

ACTAVIS ELIZABETH LLC., et al., :

Defendants. :

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Civil Action No. 10-2352 (DMC-JAD)

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ABBOTT LABORATORIES and :  
FOURNIER LABORATORIES :  
IRELAND LTD., :

Plaintiffs, :

v. :

ANCHEN PHARMACEUTICALS, INC., :

Defendants. :

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Civil Action No. 10-3015 (DMC-JAD)

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court upon the Motions for Summary Judgment filed by

Defendants Lupin Ltd., et al., Mylan Pharmaceuticals, Inc., et al., Watson Labs, Inc.-Florida, et al., Actavis Elizabeth LLC, et al., and Anchem Pharmaceuticals, Inc. (collectively, “Defendants”). ECF No. 61 in Docket 10-1578; ECF No. 61 in Docket 10-2073; ECF No. 74 in Docket 10-2139; ECF No. 57 in Docket 10-2352; and ECF No. 59 in Docket 10-3015.<sup>1</sup> Pursuant to FED. R. CIV. P. 78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of this Court that Defendants’ Motions are **denied**.

## **I. BACKGROUND**

This case concerns a pharmaceutical patent infringement suit. Plaintiffs jointly own the rights to U.S. Patent No. 7,259,186 (the “‘186 Patent”), which currently expires on Jan. 7, 2025, and claims novel salts of and formulations of fenofibric acid. Compl. ¶ 15, ECF No. 1. These salts and formulations of fenofibric acid are useful as lipid and cholesterol lowering agents for treatment of adults with increased triglyceride levels. Compl. ¶ 17. Plaintiffs market choline fenofibrate delayed release capsules under the name TRILIPIX. Compl. ¶ 18. Defendants submitted Abbreviated New Drug Applications (“ANDAs”) to the U.S. Food and Drug Administration (“FDA”), seeking approval to manufacture, use, and sell choline fenofibrate delayed release capsules as generic versions of TRILIPIX. Compl. ¶ 21. Plaintiffs thereafter filed the present suit for patent infringement. Compl. ¶¶ 25-31.

Defendants filed the present Motion for Summary Judgment on October 24, 2011, arguing that Claims One and Two of the ‘186 Patent are invalid as obvious. Plaintiffs filed their Opposition

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<sup>1</sup> The Motion filed in each docket is identical, as are the parties’ related filings. The Court will therefore refer to filings in the Lupin action, Civ. Action No. 10-1578, for the sake of ease.

papers on November 22, 2011. ECF No. 65, 66. Plaintiffs also filed related Motions to Seal Materials on November 23, 2011. Redacted versions of the documents at issue are currently available on the Court's electronic docket, and un-redacted versions of those documents are currently sealed. Defendants filed their Reply papers in support of their Motion for Summary Judgment on December 6, 2011. ECF No. 71. The matter is now before this Court.

## **II. LEGAL STANDARD**

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. See FED. R. CIV. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). The moving party bears the burden of showing that there is no genuine issue of fact. See id. "The burden has two distinct components: an initial burden of production, which shifts to the nonmoving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party." Id. The non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, but must produce sufficient evidence to support a jury verdict in his favor. See FED. R. CIV. P. 56(e); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). "[U]nsupported allegations in [a] memorandum and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). "In determining whether there are any issues of material fact, the Court must resolve all doubts as to the existence of a material fact against the moving party and draw all reasonable inferences - including issues of credibility - in favor of the nonmoving party." Newsome v. Admin. Office of the Courts of the State

of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff'd, 51 Fed. Appx. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

### **III. DISCUSSION**

Defendants seek to have Claims One and Two of the '186 Patent declared invalid. Claim One of the '186 Patent claims "[a] salt of fenofibric acid selected from the group consisting of choline, ethanolamine, diethanolamine, piperazine, calcium and tromethamine." Claim Two of the '186 Patent claims "[t]he salt of claim 1 wherein said salt is choline." Defendants assert that summary judgment is warranted on the grounds of obviousness, stating that "the asserted claims are directed to salts of a known compound, fenofibric acid, and the prior art teaches the advantages of salts selected from a limited class that are known to be pharmaceutically acceptable." Defs.' Mot. Br. 1.

To prevail on a defense of invalidity for obviousness, Defendants must demonstrate by clear and convincing evidence that:

the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a). "A party seeking to invalidate a patent based on obviousness must demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" Id. (citing Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361 (Fed. Cir. 2007)).

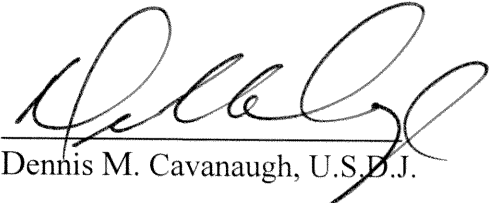
The Supreme Court has enumerated four factors to be considered by courts to assess whether an invention is obvious. Takeda v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (citing Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966)). The four factors are: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations, or “objective indicia of non-obviousness.” Id.

This Court finds that genuine issues of material fact exist in this case, including but not necessarily limited to whether the prior art motivated one of skill in the art to consider making the choline salt of fenofibric acid, and whether the prior art demonstrated that the use of the choline salt of fenofibric acid was a predictable way to improve solubility and bioavailability of fenofibrate. Accordingly, these factual disputes preclude a finding at the summary judgment stage. These disputes present exceptionally complicated questions of fact, and based on this Court’s experience, are the type of disputes best resolved at trial. Defendants’ Motion is therefore denied.

#### **IV. CONCLUSION**

For the foregoing reasons, Defendants’ Motion for Summary Judgment is **denied**. Plaintiffs’ Motion to Seal is **granted**. An appropriate Order accompanies this Opinion.

Date: February 23 2012  
Orig.: Clerk  
cc: All Counsel of Record  
Hon. Joseph A. Dickson, U.S.M.J.  
File

  
Dennis M. Cavanaugh, U.S.D.J.